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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/588,051	03/07/2007	Thomas Tallberg	U 016420-2	4058

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EXAMINER	
HUANG, GIGI GEORGIANA	
ART UNIT	PAPER NUMBER
1612	
MAIL DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/588,051	TALLBERG, THOMAS	
	Examiner	Art Unit	
	GIGI HUANG	1612	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 April 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *2-7 and 10* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *2-7 and 10* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of Application

1. The response filed April 24, 2009 has been received, entered and carefully considered. The response affects the instant application accordingly:

   a. Claims 2-5 and10 have been amended.

   b. Claim 11 has been cancelled.

2. Claims 2-7 and 10 are pending in the case.

3. Claims 2-7 and 10 are present for examination.

4. The text of those sections of title 35.U.S. Code not included in this action can be found in the prior Office action.

5. All grounds not addressed in the action are withdrawn or moot.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claim 5 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time the application was filed, had possession of the claimed invention.

The claim is drawn to the incorporation and use of neurogenic lipids for psoriasis. There is inadequate written description for the term “neurogenic lipids”. The claim also

recites that the “neurogenic lipids" are “obtained from pig brains". The specification does not provide an adequate description of what the “neurogenic lipids” are or its components. The specification does state a methodology of obtaining the neurogenic lipids such as those from the brains of young pigs including extraction but does not address what specifically is being extracted. The specification also states that the neurogenic lipids are purchased and canned by Neurofood Ltd.

This description is inadequate as there is no disclosure as to what are the specific components or lipids are used and as the “neurogenic lipids” are purchased from a commercial source with no disclosure of which specific product what purchased and utilized, it does not allow one of skill in the art to ascertain what the material is. Second, the specification states that the lipid is extracted from pig brain but there is no indication as to what was extracted, or what the resulting material is. It could be any number of materials such as fatty acids and phospholipids, but the specification does not disclose what the neurogenic lipids are. The specification also does not distinguish what the material is verses any lipid material derived from any source or synthetic form as a for example, a phospholipid is a phospholipid regardless of the source or if synthetic. Additionally, if the commercial product is trademarked, the identification/description is indefinite and does not support written description for “neurogenic lipids” as the term is not described to ascertain what the material is. Where a trademark or trade name is used to identify or describe a particular material or product, the scope becomes uncertain since the trademark or trade name cannot be used properly to identify any particular material or product. A trademark or trade name

is used to identify a source of goods, and not the goods themselves. Thus, a trademark or trade name does not identify or describe the goods associated with the trademark or trade name compounding the issue of written description.

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. Claim 5 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claim is directed to the use of neurogenic lipids for psoriasis. The claim also recites that the “neurogenic lipids" are “obtained from pig brains". It is unclear what “neurogenic lipids” are. It is unclear what materials are encompassed by the term. The specification states that the lipid is extracted from pig brain but there is no indication as to what was extracted, or what the extracted material is. It could be any number of materials, but the specification does not disclose what the neurogenic lipids are. It is also unclear what the distinction is as to where the material is from as a material derived from any source or synthetic form is still the same material, if it is clear as to what it is. Additionally, the specification addresses the neurogenic lipids are purchased and canned by Neurofood Ltd. whereby it is unclear what it is. When a trademark or trade name used to identify or describe a particular material or product, the scope becomes uncertain since the trademark or trade name cannot be used properly to identify any particular material or product. A trademark or trade name is used to identify a source of goods, and not the goods themselves. It does not allow one of skill in the art to

ascertain the metes and bounds of the invention. As a result, for purposes of prosecution, any possible lipid such as fatty acids and phospholipids or brain matter, applies.

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

11. Claims 3-7 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tallberg et al. (Studies on Mitochondrial Regulation of the Genome), in view of Bodaness (U.S. Pat. No. 5563132).

Tallberg et al. teaches compositions comprising amino acids and trace elements for bio-immunotherapy. specific components fed to a patient suffering from skin tumors (e.g. fibrotic histiocytoma, Merkel sarcoma, melanoma) comprised of isoleucine, serine, chromium, selenium, tin, vanadium, wolfram, manganese, folic acid, pig brain (neurogenic lipid), and multivitamins (see Page 134).

Additionally, Tallberg teaches the use of these compositions comprising of isoleucine, serine, chromium, selenium, tin, vanadium, wolfram, manganese, folic acid, pig brain (neurogenic lipid), and multivitamins orally for active immunotherapy to regress, heal, or transform the tumor into normal skin tissue. The trace elements are also presented in salt form.

Tallberg et al. does not expressly teach the use of these compositions for psoriasis.

Bodaness teaches that the treatment of conditions characterized with accumulations of cells such as psoriasis, skin cancers, and premalignant lesions with the same composition is known. Bodaness also teaches that the general use of metal ions such as those in the instant invention (e.g. vanadium, chromium, manganese, tin, and tungsten/wolfram) are useful for these conditions and can be administered in many forms including orally, topically, intralesionally, intravenously (Col.4, lines 39-48, Col.7, lines 33-40, Col. 11 lines 44-55, Col.15, lines 26-36, Col. 16, line 3).

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to utilize the compositions for psoriasis, as suggested by Bodaness, and produce the instant invention. It would have been obvious to utilize the composition for psoriasis as it is common in the art to utilize compositions that are useful for skin cancer/tumors for psoriasis as evidenced by Bodaness particularly as several of the metals/elements are common to both compositions.

One of ordinary skill in the art would have been motivated to do this because it is desirable to utilize a composition for other conditions when there is a suggestion in the art to use materials for skin cancer and psoriasis.

12. Claim 2 is rejected under 35 U.S.C. 103(a) as being unpatentable over Tallberg et al. (Studies on Mitochondrial Regulation of the Genome), in view of Bodaness (U.S. Pat. No. 5563132, as applied to claims 3-7 and 10 above, and further in view of Yoneda et al. (U.S. Pat. No. 5997852).

The teachings of Tallberg et al. in view of Bodaness are addressed above.

Tallberg et al. in view of Bodaness does not expressly teach the incorporation of zinc.

Yoneda et al. teaches the administration of zinc (i.e. oral) and fatty acids for treating several conditions including psoriasis. Yoneda also teaches that psoriasis is linked to zinc deficiency and the composition can include other components such as minerals, vitamins, and amino acids (Abstract, Col. 1 line 1-28, Col. 2 line 10-35, 50-58, Col. 3 line 10-25).

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to include zinc in a composition for psoriasis, as suggested by Yoneda, and produce the instant invention. It would have been obvious to combine two compositions each of which is taught by prior art to be useful for same purpose in order to form third composition that is to be used for very same purpose; the idea of combining them flows logically from their having been individually taught in prior art.

One of ordinary skill in the art would have been motivated to do this because it is desirable to have improved and additive effects for treating a condition.

13. Claims 3-7 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tallberg et al. (Studies on Mitochondrial Regulation of the Genome), in view of Ghosh et al. (U.S. Pat. 6268398).

Tallberg et al. teaches compositions comprising amino acids and trace elements for bio-immunotherapy, specifically for affecting the mitochondrial membrane and mitochondrial regulation and normalization in cancer treatment. Specific components

are fed to a patient suffering from skin tumors (e.g. fibrotic histiocytoma, Merkel sarcoma, melanoma) comprised of isoleucine, serine, chromium, selenium, tin, vanadium, wolfram, manganese, folic acid, pig brain (neurogenic lipid), and multivitamins (see Page 134).

Additionally, Tallberg teaches the use of these compositions comprising of isoleucine, serine, chromium, selenium, tin, vanadium, wolfram, manganese, folic acid, pig brain (neurogenic lipid), and multivitamins orally for active immunotherapy to affect mitochondrial changes to regress, heal, or transform the tumor into normal skin tissue. The trace elements are also presented in salt form.

Tallberg et al. does not expressly teach the use of these compositions for psoriasis.

Ghosh et al. teaches that there are mitochondria-associated diseases such as cancer and psoriasis and that the concept of treatments directed to mitochondria-associated diseases is known (Abstract, Col. 9 line 35-58, Claim 1, 13, 18).

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to utilize the compositions for psoriasis, as suggested by Ghosh, and produce the instant invention. It would have been obvious to utilize the composition for psoriasis as Tallberg teaches that the composition is regulating mitochondria to produce normal tissue in cancer which is a mitochondria-associated disease, Ghosh teaches that psoriasis and cancer are both mitochondria-associated diseases and that the concept of treatments directed to different types of mitochondria-associated diseases are known, whereby it would be obvious to one of skill in the art to

use the composition for other conditions such as psoriasis that are mitochondria-associated diseases to affect/regulate the mitochondria with a reasonable expectation of success.

One of ordinary skill in the art would have been motivated to do this because it is desirable to utilize a composition to treat other related conditions such as other mitochondria-associated diseases when there is a suggestion in the art that the conditions are related and there are treatments directed to mitochondria-associated diseases such as psoriasis and cancer as it is desirable to treat as many conditions and patient populations possible.

14. Claim 2 is rejected under 35 U.S.C. 103(a) as being unpatentable over Tallberg et al. (Studies on Mitochondrial Regulation of the Genome), in view of Ghosh et al. (U.S. Pat. 6268398) as applied to claims 3-7 and 10 above, and further in view of Yoneda et al. (U.S. Pat. No. 5997852).

The teachings of Tallberg et al. in view of Ghosh are addressed above.

Tallberg et al. in view of Ghosh does not expressly teach the incorporation of zinc.

Yoneda et al. teaches the administration of zinc (i.e. oral) and fatty acids for treating several conditions including psoriasis. Yoneda also teaches that psoriasis is linked to zinc deficiency and the composition can include other components such as minerals, vitamins, and amino acids (Abstract, Col. 1 line 1-28, Col. 2 line 10-35, 50-58, Col. 3 line 10-25).

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to include zinc in a composition for psoriasis, as suggested by Yoneda, and produce the instant invention. It would have been obvious to combine two compositions each of which is taught by prior art to be useful for same purpose in order to form third composition that is to be used for very same purpose; the idea of combining them flows logically from their having been individually taught in prior art.

One of ordinary skill in the art would have been motivated to do this because it is desirable to have improved and additive effects for treating a condition.

Response to Arguments

15. Claim 5 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is regards to the term “neurogenic lipids”.

Applicant's arguments filed 2/24/2009 and 4/24/2009 have been fully considered but are not persuasive. Applicant asserts that the term is understood by one of the art to be one that was extracted from the nervous system. This is not persuasive as the specification does not provide a written description of what are neurogenic lipids. The claim attempts to describe the lipids by where they *are from* but not what they *are*. As the matter is processed and extracted, it is not described as what was the material used. There is no description as to what the lipid is. Is it an EPA, GLA, sphingomyelin, phosphatidylcholine, phosphatidylethanolamine, phosphatidylethanolamine, ALA, DHA, LA? Is it a mix? Is there elemental extracts? Is there protein matter in trace amounts? Is there cholesterol? Is it a fat? There is no description addressing what the neurogenic lipid is.

Additionally, stating where a material is obtained from does not distinguish what the material is verses a material derived from any other source or synthetic form as a for example, a phospholipid is a phospholipid regardless of the source or if synthetic.

The specification only states the neurogenic lipids are purchased and canned by Neurofood Ltd. Whereby there is no disclosure as to what are the specific components or lipids are used and as the "neurogenic lipids" are purchased from a commercial source with no disclosure of which specific product what purchased and utilized, whereby it does not allow one of skill in the art to ascertain what the material is. Second if the commercial product is trademarked, the identification/description does not provide adequate written description as it is indefinite. Where a trademark or trade name is used to identify or describe a particular material or product, the material becomes uncertain since the trademark or trade name cannot be used properly to identify any particular material or product. A trademark or trade name is used to identify a source of goods, and not the goods themselves. Thus, a trademark or trade name does not identify or describe the goods associated with the trademark or trade name.

Accordingly, the rejection is maintained.

16. Claims 3-7 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tallberg et al. (Studies on Mitochondrial Regulation of the Genome), in view of Bodaness (U.S. Pat. No. 5563132).

Applicant's arguments filed 2/24/2009 and 4/24/2009 have been fully considered but they are not persuasive. In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references

individually where the rejections are based on combinations of references. Applicant asserts that the etiology and pathophysiology of psoriasis and skin cancer are different and that Tallberg does not teach the composition for psoriasis and are directed to the biochemical pathways of mitochondria. The Examiner does not contest that the two conditions present differently, however the art teaches that it is known in the art that compositions for treatment for one condition can be applied to the other. It is noted that Applicant's recitation that the etiology of the two are different is inaccurate as the specific etiology (cause) for psoriasis and skin cancers such as Merkel's is not known and cannot be said to be distinct (see Merck- Epidemiology and Etiology, and the National Cancer Institute-question 3). Additionally, it is known in the art that the two conditions are mitochondria-associated (see Ghosh) which goes to Tallberg's methodology for skin cancer.

As for Bodaness, Applicant's arguments are directed the assertion that there is no suggestion for the use of any amino acid for psoriasis whereby as addressed above, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. As for the argument that the metal ion is not use to treat the conditions but that the reaction product of the peroxide and the metal-ion compound is the species that destroys the cancer, is considered but not persuasive. The use of Bodaness is to show that the use of a composition for one of the condition such as cancer is also known in the art to be useful for other conditions characterized with accumulations of cells such as psoriasis and it would be obvious to one of skill in the art to utilize a composition useful for cancer would try and use it for

another related condition characterized with accumulations of cells such as psoriasis. It is also to show that the metal ions are generally used in such treatments and not unheard of and not for selecting a metal from Bodaness for treatment as stated by Applicant. As for the argument that the reference mentions oral administration but the topical modality is described in the reference is not persuasive as the general teaching for administering a composition for these conditions includes oral.

In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

Accordingly, the rejection is maintained.

17. Claim 2 is rejected under 35 U.S.C. 103(a) as being unpatentable over Tallberg et al. (Studies on Mitochondrial Regulation of the Genome), in view of Bodaness (U.S. Pat. No. 5563132, as applied to claims 3-7 and 10 above, and further in view of Yoneda et al. (U.S. Pat. No. 5997852).

Applicant's arguments filed 2/24/2009 and 4/24/2009 have been fully considered but they are not persuasive. Applicant's arguments to Tallberg and Bodaness are addressed above. The argument to Yoneda that one would not arbitrarily pick zinc out

of the reference is not persuasive as the composition is directed to zinc and fatty acids are the actives which can be incorporated with the composition in Tallberg in view of Bodaness, as it is obvious to combine two compositions for the same purpose to form a third composition for the same purpose.

Accordingly, the rejection is maintained.

Conclusion

18. Claims 2-7 and 10 are rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to GIGI HUANG whose telephone number is (571)272-9073. The examiner can normally be reached on Monday-Thursday 8:30AM-6:00PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Fredrick Krass can be reached on 571-272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

GH
/Zohreh A Fay/
Primary Examiner, Art Unit 1612